21 CFR Part 39 Airworthiness Directives; Pratt & Whitney PW4000 Series Turbofan Engines; Correction

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; correction.

SUMMARY: This document makes a correction to Airworthiness Directive (AD) 2003–19–15, applicable to Pratt & Whitney PW4000 series turbofan engines. AD 2003–19–15 was published in the Federal Register on September 30, 2003 (68 FR 56143). In the amendatory language, under § 39.13 [Amended], the amendment number of the new action was inadvertently omitted. This document corrects that omission. In all other respects, the original document remains the same.

EFFECTIVE DATE: October 9, 2003.


SUPPLEMENTARY INFORMATION: A final rule airworthiness directive, FR Doc. 03–24486, applicable to Pratt & Whitney PW4000 series turbofan engines, was published in the Federal Register on September 30, 2003 (68 FR 56143). The following correction is needed:

On page 56145, in the second column, under § 39.13 [Amended], in the sixth line, add “Amendment 39–13318,” after “Pratt & Whitney”.

Issued in Burlington, MA, on October 3, 2003.

Jay J. Pardee,
Manager, Engine and Propeller Directorate, Aircraft Certification Service.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 347

Food and Drug Administration

RIN 0910–AA01

Skin Protectant Drug Products for Over-the-Counter Human Use; Astringent Drug Products; Final Monograph; Direct Final Rule; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of October 27, 2003, for the final rule that appeared in the Federal Register of June 13, 2003 (68 FR 35290). The direct final rule amends the regulation that established conditions under which over-the-counter (OTC) skin protectant astringent drug products are generally recognized as safe and effective and not misbranded. This action revises some labeling for astringent drug products to be consistent with the final rule for OTC skin protectant drug products (68 FR 33362, June 4, 2003) and adds labeling for certain small packages (stypic pencils). This document confirms the effective date of the direct final rule. This action is part of FDA’s ongoing review of OTC drug products.


FOR FURTHER INFORMATION CONTACT: Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD–560); Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2307.

SUPPLEMENTARY INFORMATION: In the Federal Register of June 13, 2003 (68 FR 35290), FDA solicited comments concerning the direct final rule for a 75-day period ending August 27, 2003. FDA stated that the effective date of the direct final rule would be on October 27, 2003, 60 days after the end of the comment period, unless any significant adverse comment was submitted to FDA during the comment period. FDA did not receive any significant adverse comments.


Accordingly, the amendments issued thereby are effective.


Jeffrey Shuren,
Assistant Commissioner for Policy.

For the reasons explained herein, the Postal Service adopts the proposal, with minor modifications. The proposal provided background concerning Nonprofit Standard Mail eligibility; the traditional role of Congress in expansion of eligibility for these rates; the history of the cooperative mail rule; and its application to fundraising mailings; recent concerns...
raised by nonprofit representatives concerning application of the cooperative mail rule on fundraising mail and potential effects on nonprofit organizations; and proposed legislation to exempt certain fundraising mail from application of the rule. The proposal also explained the Postal Service’s reluctance to propose a rulemaking on these issues since expansion of eligibility for nonprofit rates has traditionally been accomplished through legislation. Nevertheless, as the proposal discussed, the Postal Service determined to embark upon this rulemaking with the understanding that it represented the consensus of parties with an interest in nonprofit issues, including bipartisan Congressional support, representatives of both nonprofit organizations and professional fundraisers, and the Postal Service; that it was needed to assist nonprofit organizations in obtaining support necessary to fund their programs; and that this result could be accomplished more quickly administratively than legislatively.

The Postal Service received 67 comments concerning its proposal, including one that was received late but was considered. The commenters were diverse, including nonprofit organizations and organizations representing such organizations; professional fundraisers and organizations representing these commercial entities; Congressional representatives; private individuals; and an organization representing state officials that regulate charities. The comments also presented a broad range of views. A significant majority of the comments urged the Postal Service to adopt the rule as proposed. A small number of comments, concerned with potential abuses, recommended limitation of the proposed rule. Of these commenters, a small number recommended that the Postal Service withdraw the proposal, while the remainder recommended that it be adopted with additional restrictions. In contrast, a lesser number of comments recommended the exemption from application of the cooperative mail rule be expanded even further. Additionally, several comments recommended that the rule should be retroactive.

One of the comments that urged withdrawal of the rule argued that the rule would primarily benefit commercial fundraisers, rather than nonprofit organizations, while the other spoke more generally of potential abuse. If the former assertion were proven to be true, it would give the Postal Service reason to consider withdrawing the proposal. That is, the Postal Service understands that the primary concern of Congress and the nonprofit industry in seeking changes in this area was to benefit nonprofit organizations. Admittedly, the Postal Service does not have independent knowledge to verify the accuracy of the commenter’s claims, since the Postal Service does not monitor or regulate the business relationships between nonprofit organizations and professional fundraisers. The comment did not provide evidence to substantiate its claim. Moreover, both nonprofit organizations and associations representing them, who obviously have an interest in this question, urge adoption of the proposal or a modified version of it. This suggests, and some of these comments specifically state, that the change will benefit at least some nonprofit organizations. Accordingly, the Postal Service does not find it appropriate to reject the proposal, as urged by this comment.

The comments that urge the imposition of restrictions narrowing the proposed exemption from the cooperative mail rule do so for reasons related to those raised by comments seeking withdrawal of the proposal. That is, although they do not urge rejection of the new policy, these comments express concern that some professional fundraisers may use the new rules to take advantage of inexperienced or unsophisticated nonprofit organizations.

At the outset, it should be noted that the proposed rule does not dictate the terms of the relationship between nonprofit organizations and fundraisers. If anything, it increases the options available to the parties. For instance, it does not prevent nonprofits from entering the type of principal-agent relationship with fundraisers contemplated by the cooperative mail rule. And, as urged by the numerous parties that sought the Postal Service rulemaking in this area, it allows the nonprofits to consider other relationships to retain the services of professional fundraisers.

The Postal Service does not doubt that the proposed change in its standards will provide individual nonprofit organizations the freedom to enter agreements that, in hindsight, at least a few will conclude to have been unwise. However, the Postal Service does not believe that this provides the justification, at least at this time, to adopt the additional restrictions urged by some comments. Those proposals recommend that the Postal Service require nonprofits and fundraisers to adhere, and certify their compliance, to a variety of conditions concerning their relationship. The conditions suggested include: (1) A restriction against any officer, director, principal, or fiduciary of the party that is ineligible to mail at nonprofit rates (hereafter “ineligible participant”) or a corporate affiliate or close relative of the ineligible participant serving as an officer, director, or key employee of the nonprofit; (2) a requirement that the arrangement between the nonprofit and ineligible participant be governed by a written contract, and that this contract be signed by a board member or officer of the nonprofit; (3) a requirement that the donations be deposited in a bank account under the nonprofit’s exclusive control; (4) a requirement that the ineligible participant have no ownership or control over the list of donors responding to the solicitation, beyond a limited contingent security interest; (5) a requirement that the ineligible participant not retain ownership rights to intellectual property in the fundraising package developed at the nonprofit’s expense; (6) a requirement that, in instances where the ineligible participant extends credit to the nonprofit, the credit terms are not conditioned upon the continued employment of the ineligible participant; and (7) a requirement that the mailing not constitute an excess benefit transaction as defined by the Internal Revenue Service. As explained, the Postal Service has determined to adopt the fourth suggestion, in part. Other than that item, for the reasons discussed below, the Postal Service has determined not to adopt the restrictions suggested by these commenters.

First, based on comments received by the Postal Service, it is clear there is significant disagreement as to whether any, much less these, additional restrictions should be adopted. As discussed above, and in the earlier Federal Register notice, the Postal Service proposed its rule change reluctantly, based on an understanding there was a broad consensus among interested parties supporting it. Although there appears to remain a general consensus in support of the proposal, there is no consensus supporting any of the suggested additional restrictions.

Second, even if the Postal Service found it appropriate to consider additional postal standards in this area, it is not convinced that the standards suggested are necessarily appropriate. The Postal Service understands the nonprofit universe to be diverse. For example, nonprofits may be large or small, well-established or relatively new, relatively well-funded or not well-funded, run by a permanent paid staff
or all-volunteer. It seems to us difficult
to impose a set of restrictions that
should be universally applied to all of
these organizations. However, that is
what the comments suggest.

Third, even if the terms suggested by
the commenters are reasonable, the need
to impose them by regulation is not
clear to the Postal Service. That is,
although the need to ensure that
nonprofit organizations are not subject
to abuses by commercial entities is a
laudable objective, it might be
accomplished, or at least attempted,
through alternatives to regulation. For
example, education or training of
nonprofits may prove to be sufficient,
particularly if it is true that adherence
to the suggestions is financially
beneficial for the nonprofit. There are a
number of interested entities that might
provide this education and training:
associations representing nonprofit
organizations; associations representing
fundraisers; and government entities
that regulate professional fundraisers
and nonprofits. The Postal Service
encourages these associations and
government agencies to undertake
efforts to educate nonprofit
organizations and to take other
appropriate measures to protect
nonprofits from potential abuses. We
also encourage nonprofit organizations
to utilize these resources and to review
their existing and proposed fundraising
arrangements and consider whether the
terms of those arrangements are in their
best interests. The Postal Service will be
happy to assist, as appropriate, in these
efforts.

Fourth, the Postal Service also has
doubts that the procedures suggested by
some of the comments are
administratively feasible. The comments
did not appear to suggest that the Postal
Service undertake the difficult task of
independently verifying mailers’
compliance with the proposed
conditions. Rather, they suggested that
the parties each sign the postage
statements certifying compliance with
the new standards and that the Postal
Service rely upon these statements.
However, the Postal Service does not
require all parties to sign the postage
statement at this time and, when
analogous proposals have been raised in
the past, mailers have pointed out the
logical problems they would face if
required to sign postage statements for
mail prepared and entered by their
agents. Moreover, even if it is not
contemplated by the commenters that
the Postal Service will seek to enforce
the suggested conditions beyond
ensuring that the parties sign the
postage statement, it is unlikely that the
Postal Service can avoid all other
enforcement activity. For instance, if it
is alleged that parties are not in
compliance, despite mailing at the
nonprofit rates while certifying they did
comply, it is likely that the Postal
Service would be expected to
investigate the assertions. Unlike
violations of the current cooperative
mail rule, which often can be
determined by examination of the
parties’ contractual arrangements, some
of the proposed conditions would likely
require a more extensive investigation.
For example, the restriction against
officers and others with close ties to the
ineligible participant (including the
close relatives of these individuals)
serving as officers, directors, or key
employees of the nonprofit would
require an exhaustive examination of
the organization charts and employment
rolls of each organization. Determining
whether there is a violation of the IRS
excess benefit transaction standard
would require Postal Service employees
to develop expertise in these standards
and to obtain the information needed to
apply them. Given the possibility of IRS
investigations of the parties under the
same standard, this requirement would
create the risk of duplicative
government efforts.

There is also the likelihood that the
proposed conditions will create
practical, administrative hardships for
some nonprofits. For example, the
requirement that the donated funds be
deposited in a bank account controlled
exclusively by the nonprofit could
prove difficult for nonprofits that,
because of size or other concerns, are ill-
equipped to handle such accounts.
Similarly, the requirement that the
board members or officers sign
fundraising agreements could create
difficulties for organizations that
disburse funds to other parties. As the Postal Service is aware
from its own purchasing procedures, it
is not unusual for employees that are
not officers to be given authority to sign
contracts.

Adoption of the proposed conditions
also could work to the financial
detriment of some nonprofits. The
proposed rule provides additional
options for nonprofits, thereby giving
them additional choices in their efforts
to find the arrangement that will
maximize the benefit to the nonprofit.
For instance, it may be beneficial for
some nonprofits to consider
arrangements concerning donor lists,
intellectual property rights, and credit
terms beyond those that would be
permitted under the proposed
conditions. Limiting the choices
available to nonprofits might, in some
instances, take away the option that
would be best for some organizations.
Of course, it could be argued that
increasing the options available to
nonprofits will increase the likelihood
that some, particularly the least
sophisticated, will make the wrong
choice. However, as observed above, the
appropriate safeguard against this
possibility would seem to be the
education of nonprofits to make the best
choices in their particular
circumstances, rather than eliminating
options that might be prove to be the
best choice for some of them.

Finally, the Postal Service is
central to that adoption of the proposed
conditions may create conflicts with
state or federal statutes and that, if such
conflicts occur, mailers would be placed
in the untenable position of determining
whether to comply with the statutes or
with postal regulations. Indeed, as
discussed in the notice announcing the
proposed rule in 65 FR 23939, ensuring
that our customers “do not
unintentionally violate the laws of those
states that regulate the financial
arrangements between nonprofits and
certain types of professional
fundraisers” was one of the motives
underlying the rulemaking. The Postal
Service is aware that all states have
terms that regulate the relationship between
professional fundraisers and their nonprofit clients.
At the present time, it appears that at
least 28 states have enacted some type
of financial distribution requirement on
fundraisers and, if anything, we understand that the trend toward
such state oversight is increasing.
Additionally, there are a number of
federal agencies with the authority and
expertise to enact and enforce standards
concerning these relationships, such as
the Federal Trade Commission, Internal
Revenue Service, and Department of
Justice. Under an exemption of
fundraising mailings from the
cooperative mail rule, the states and
federal agencies will be able to adopt
and enforce their standards without
concern that such action might be in
conflict with postal rules.

As alluded to above, the Postal
Service has determined to adopt a
condition concerning donor lists (i.e.,
the lists of persons contributing donations in response to the solicitation). Under this condition, the exemption from application of the cooperative mail rule will apply only where the nonprofit organization is given a list of the donors, contact information for those persons, and the amount of their donations. Based on past reviews of fundraising agreements, the Postal Service believes that this condition is already generally followed in the fundraising industry. Moreover, compliance with this condition generally can be determined by postal officials from review of the agreement between the fundraiser and the nonprofit. Finally, to guard against the possibility that some nonprofits will be better served financially if not subject to this condition, postal standards will allow them to waive the receipt of this listing, as long as that is done in writing.

Based on these considerations, the Postal Service has determined not to adopt at this time the remaining restrictions suggested by some comments. Nevertheless, they do raise significant concerns and the Postal Service’s Consumer Advocate will monitor implementation of the rule to determine whether abuses are occurring. As promised in the proposal, if such abuses or other unintended consequences occur after the rulemaking, the Postal Service will consider a further rulemaking or other administrative actions.

Several commenters, although in favor of the proposal, assert that the rulemaking did not go far enough. They assert that the exemption from the cooperative mail rule should also cover the sale of products and services, at least those of nominal value, as well as a variety of documents including brochures, thank you letters, letters confirming the amount of donations, newsletters, and “chase” letters. The Postal Service understands the latter to refer to letters that follow up on telemarketing fundraising campaigns and remind donors that their pledges have not been paid. Assuming that understanding of “chase” letters is correct, the Postal Service considers them to be a solicitation for monetary donations within the proposal. Accordingly, as long as they do not contain other disqualifying material, such letters would be exempt from application of the cooperative mail rule.

The Postal Service has determined not to expand the proposal to provide that pieces promoting the sale of products and services also be exempt from application of the cooperative mail rule. As explained in the proposal, the exemption is strictly limited to fundraising mailings seeking monetary donations and does not apply to mailings promoting any goods or services. The suggestion goes beyond the consensus agreement that led to the rulemaking. Moreover, as the Postal Service explained in the notice discussing the proposal, adoption of the suggestion would create significant potential for abuse by commercial organizations and may place small businesses and other for-profit organizations who sell similar goods and services at a competitive disadvantage. The suggestion that the proposal be expanded to cover only products and services of nominal value does not alter these considerations; if anything, it could create concerns in administering what is included within that standard.

The Postal Service also has determined not to expand this rulemaking to cover the other documents (e.g., thank you letters, newsletters, confirmations of donations) identified in the comments. These suggestions are beyond the scope of the rulemaking as well as the consensus favoring the exemption of certain fundraising mailings from application of the cooperative mail rule. Moreover, the need for a rulemaking to address these documents is unclear. The Postal Service is not aware of any general concern regarding its policies involving these documents. Some of them may, in fact, be generally sent as First-Class Mail, and thereby they are not eligible for Nonprofit Standard Mail rates in any case.

Finally, several commenters suggest that the proposed policy be made retroactive. The Postal Service has determined not to do so and, as explained in its proposal, the change in policy is prospective only, effective on the date of enactment. A retroactive change could open the Postal Service to an undefined number of refund claims.

For these reasons, the Postal Service adopts the rule as proposed but, in addition to the condition described above, makes three minor changes. First, the proposed revision was to apply only to nonprofit organizations authorized to mail at the nonprofit rates. The rule is changed to apply to all customers authorized to mail at Nonprofit Standard Mail rates. Second, the proposed rule is revised to make clear that the exception from application of the cooperative mail rule applies only where the monetary donations solicited are for the entity authorized to mail at nonprofit rates. Finally, the language is revised to make clear that the exception is prospective only.

List of Subjects in 39 CFR Part 111
Administrative practice and procedure, Postal Service.

PART 111—[AMENDED]

1. The authority citation for 39 CFR part 111 continues to read as follows:


2. Add the following to Domestic Mail Manual section E6705.3: “Exception: effective November 13, 2003, this standard no longer applies to mailings by an organization authorized to mail at Nonprofit Standard Mail rates soliciting monetary donations to the authorized mailer and not promoting or otherwise facilitating the sale or lease of any goods or service. This exception applies only where the organization authorized to mail at Nonprofit Standard Mail rates is given a list of each donor, contact information (e.g., address, telephone number) for each, and the amount of the donation or waives in writing the receipt of this list.”

An appropriate amendment to 39 CFR part 111 to reflect these changes will be published.

Stanley F. Mires,
Chief Counsel, Legislative.

[FR Doc. 03–25643 Filed 10–8–03; 8:45 am]

BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52
[ NM–46–1–7615a; FRL–7571–1]

Approval and Promulgation of Implementation Plans; New Mexico; Revision to Motor Vehicle Emission Budgets in Bernalillo County, New Mexico Carbon Monoxide Air Quality Maintenance Plan Using MOBILE6

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The EPA is taking direct final action approving the State Implementation Plan (SIP) revisions for Bernalillo County, New Mexico, which is a carbon monoxide maintenance area. This SIP revision was submitted to EPA by the Governor of New Mexico on May 15, 2003. More specifically, EPA is approving the county’s revised Motor Vehicle Emissions Budget (MVEB) for carbon monoxide (CO) for 1996, 1999, 2002, 2005 and 2006. This budget was developed using EPA’s latest emissions